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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,473	05/31/2000	BARBARA BOTTAZZI	2801-18	9420

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EXAMINER
JAMROZ, MARGARET E

ART UNIT	PAPER NUMBER
1644	17

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/555,473	Applicant(s) BOTTAZZI ET AL.	
	Examiner Margaret E Jamroz	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 12-16* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment, filed 3/20/2002 (Paper No. 16), is acknowledged.

Claims 1-8 and 12-16 are pending.

Claims 6-8 and 12-16 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a non-elected invention.

Claims 1-5 are under consideration in the instant application.

Foreign Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

3. The drawings stand objected to because of the errors listed on the PTO-948; therefore, the drawings fail to comply with 37 CFR 1.84.

The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

In view of the amendment filed 03/20/2002, the following rejections remain.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons as set forth in Paper No. 14, mailed 12/20/2001.

Applicant's arguments filed 03/20/3002 have been fully considered but they are not persuasive. Applicant's opinion is that the claims are not indefinite and invites the examiner to more specifically point out items to be corrected.

It is the examiner's opinion remains that the claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Specifically, a claim should be a complete sentence. Independent claim 1 should start with "A" or "An", and dependent claims 2-5 should start with "The".

In claim 1, line 2, the comma after "containing" should be deleted, the word "an" should be inserted prior to "active", and in line 3, the comma after "PTX3 should be deleted as it is unnecessary.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a single human PTX3 protein (i.e. SEQ ID NO: 1) cloned into a murine mastocytoma cell line and injected into a mouse to show anti-tumor activity, does not reasonably provide enablement for the genus of the protein PTX3 for the treatment of the genus of tumors and infectious and inflammatory diseases, or for the treatment of any bacteria, any protozoa, or the genus of fungi. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the same reasons as set forth in Paper No. 14, mailed 12/20/2001.

Applicant's position is that:
(1) "carboxymethylcellulose is an acceptable pharmaceutical excipient,
(2) the specification discloses on page 2, lines 1-23 and page 3, lines 1-5 that the degree of identity between the human and mouse PTX3 amino acid sequences is 82% and reaches 90% if conservative substitutions are considered. The high degree of similarity between the human and murine PTX3 sequences is a sing of the high degree of conservation of pentraxin during evolution, and
(3) data is submitted on pages 6-11 of the amendment that PTX3 was capable of treating mice infected with the invasive pulmonary aspergillosis, Aspergillus fumigatus.

It is the examiner's opinion that:
(1) The disclosure of carboxymethylcellulose is sufficient to support the claimed pharmaceutical composition in view of the Merck reference submitted by applicant on 03/20/2002.

(2) The disclosure of a single human PTX3 protein (i.e. SEQ ID NO: 1), even in light of the amino acid homology applicant disclosed in the amendment and the specification cannot support the genus of PTX3 amino acid sequences. As is set forth on pages 4-5 of Paper No. 14, mailed 12/20/2001, Mikayama et al. teach that even a single amino acid change can completely change the function of a protein. Therefore, applicant has not taught one skilled in the art the genus of long pentraxin PTX3 proteins (naturally occurring or otherwise) other than SEQ ID NO: 1.

(3) The examiner acknowledges the data submitted showing that applicant shows in Figure 1 that PTX3 is bound to the fungus *Aspergillus fumigatus*, but was not bound to another fungus, *Candida albicans*, which leads the examiner to believe that the PTX3 protein would not be capable of treating the genus of fungi as claimed. Data based on a single fungus (i.e. *Aspergillus fumigatus*) cannot support the genus of fungi, and cannot be extrapolated to the treatment of any bacteria, any protozoa, or any virus, much less the genus of infectious and inflammatory diseases. Further, a single instance of anti-tumor activity by cloning human PTX3 into the murine mastocytoma P815 cell line which is then injected into mice as disclosed in the specification on page 9, line 3 cannot support the treatment of the genus tumors.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Claims 1-5 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons as set forth in Paper No. 14, mailed 12/20/2001.

Applicant's position is the same with respect to the scope of enablement rejection set forth above.

The examiner's position is also the same as set forth above in response to applicant's arguments. The disclosure of a single SEQ ID NO cannot support the genus of PTX3 proteins and the single instance of anti-tumor activity by cloning human PTX3 into the murine mastocytoma P815 cell line which is then injected into mice as disclosed in the specification on page 9, line 3 cannot provide written description support for the treatment of the genus tumors, and that the single disclosure of a pharmaceutical composition comprising human PTX3 to treat *A. fumigatus* invasiveness cannot provide written description support for the genus of fungi, or extrapolate treatment of any bacteria, protozoa, or virus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Alles et al. (blood, 1994. 84(10: 3483-3493), of record, for the same reasons as set forth in Paper No. 14, mailed 12/20/2001.

Applicant's position is that the Alles et al. reference does not teach a pharmaceutical composition and specifically points to pages 3483 and 3485 regarding the production of antibodies.

It is the examiner's opinion that Applicant admits on the record on page 13, paragraph 2 of the amendment filed 3/20/2002 that the gel slice containing recombinant human PTX3 was excised, mechanically disrupted in **saline**, and injected subcutaneously (SC) into a 28-day-old-rabbit.

Specifically, it is the examiner's opinion that saline has been a pharmaceutically acceptable excipient for quite a long time, and is considered a pharmaceutical composition. Therefore, the Alles et al. reference anticipates the claimed invention.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
May 14, 2002

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